DEPARTMENT OF THE ARMY
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 98-11

28 April 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE(HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Armed Forces Epidemiological Board Recommendation Regarding Deviation from the Anthrax Vaccine Policy

1. At the Armed Forces Epidemiological Board (AFEB) meeting on 15 April 1998, the Infectious Disease Control Subcommittee reviewed a draft of a DoD policy for deviation from the anthrax vaccine immunization schedule. In addition, the subcommittee reviewed the extant data available on this issue, including the original FDA licensure trials and two post Gulf War studies (one small, one large) of post-immunization antibody levels.

2. These studies demonstrated that by day 35 after three doses of vaccine, 90-95% of all individuals had developed presumptively protective levels of antibody. Further, a single booster dose given one to two years after initial receipt of one to three doses produced rapid antibody responses; 99.3% of volunteers responded 30 days after administration of this booster dose with a greater than four-fold increase in titer, and 95% of subjects demonstrated an anthrax PA titer of 1:10,000. In the largest prospective study of DOD personnel (n=604), reported on 24 October 1997, the investigators concluded that it would be "reasonable to prime with two or three doses of anthrax vaccine and boost at some reasonable interval or when deployment or travel demands it."

3. Full immunization with anthrax vaccine adsorbed requires six doses, referred to as the primary series, administered over 18 months. Doses are administered according to the following FDA approved schedule: 0, 2 and 4 weeks; 6, 12 and 18 months. Yearly boosters are administered thereafter to maintain immunity. This schedule is the only regimen shown to protect humans against anthrax. Although the effect of specific deviations from this schedule on the efficacy of the vaccine is unknown, in general, the greater the deviation the less certain the protective effect in humans.

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4. Repeating all or part of the primary series is rarely indicated. In accordance with the guidelines of the Advisory Committee on Immunization Practices, U.S. Public Health Service, an interruption in the immunization schedule does not generally require reinstitution of the entire series of a vaccine. For anthrax vaccine, this approach is supported by unpublished data in humans that shows a robust antibody response to anthrax vaccine one to two years after a partially completed primary series. However, the subcommittee recognizes that the consequences of inhalation anthrax area severe, and the correlation between serum anthrax and antibody titers and protection in humans is uncertain.

5. After consideration and discussion of these studies, the Subcommittee made the following recommendations based on the available data:

a. DO NOT ADMINISTER DOSES OF THE VACCINE ON A COMPRESSED OR ACCELERATED SCHEDULE (FOR EXAMPLE, SHORTER INTERVALS BETWEEN DOSES OR MORE DOSES THAN REQUIRED).

b. FOR LATE OR MISSED DOSES, THE FOLLOWING PROCEDURE, MAY BE FOLLOWED FOR INDIVIDUAL VARIATION FROM THE STANDARD IMMUNIZATION SCHEDULE.

1) IF ONLY ONE DOSE HAS BEEN RECEIVED, AND MORE THAN TWO YEARS HAVE ELAPSED, RESTART THE PRIMARY SERIES WITH THE FIRST DOSE. IF TWO OR FEWER YEARS HAVE ELAPSED, CONTINUE THE PRIMARY SERIES WITH THE SECOND DOSE.

2) IF TWO OR MORE DOSES HAVE BEEN RECEIVED, THE PRIMARY SERIES DOES NOT NEED TO BE RESTARTED, BUT MAY SIMPLY RESUME WITH ADMINISTRATION OF THE NEXT DOSE IN THE SERIES.

3) IF AN ANNUAL BOOSTER IS NOT RECEIVED ON TIME, ADMINISTER THE BOOSTER DOSE AT THE EARLIEST POSSIBLE DATE, ADJUSTING THE SUBSEQUENT BOOSTER DOSE SCHEDULE ACCORDINGLY. ONCE THE PRIMARY SERIES OF SIX DOSES IS COMPLETE, THE PRIMARY SERIES IS NEVER REPEATED, EVEN IF MORE THAN THREE YEARS HAVE ELAPSED BETWEEN BOOSTER DOSES.

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c. FURTHER, THE COMMITTEE STRONGLY RECOMMENDS THAT STUDIES BE DESIGNED AND INITIATED TO DETERMINE THE IMMUNOGENICITY OF AN ABBREVIATED IMMUNIZATION SCHEDULE AND THE OPTIMAL TIME INTERVAL AND NEED FOR BOOSTER DOSES OF VACCINE.

6. The above recommendation was unanimously approved by the Subcommittee.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

GREGORY A. POLAND, M.D.
Chairman, Infectious
Disease Subcommittee

VICKY L. FOGELMAN
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AFEB Executive Secretary

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